Health Information Technology Advisory Committee

The Office of the National Coordinator for Health Information Technology

U.S. Core Data for Interoperability Task Force 2021
Report to the Health Information Technology Advisory Committee

PHASE 3 - RECOMMENDATIONS ON ONC PRIORITIES FOR THE USCDI VERSION 3 SUBMISSION CYCLE

September 9, 2021

Table of Contents

Background

Leveraging significant input from the Health IT Advisory Committee and its United States Core Data for Interoperability (USCDI) Task Force, in March 2020, ONC published USCDI version 1, a standardized set of health data classes and constituent data elements for nationwide, interoperable health information exchange. The USCDI Task Force further provided recommendations on the expansion process ONC established to develop newer versions of USCDI that could be adopted by health IT developers and provided to their customers to improve interoperable health information exchange and patient access to their data. These recommendations included how to implement the ONC New Data Element and Class (ONDEC) submission system which received over 600 recommendations for new data elements for USCDI Version 2 (v2) in 2020.

On January 12, 2021, ONC published its Draft USCDI version 2 and sought public feedback on data classes and elements included in this version, as well as on data elements that ONC did not include in it. As part of this public feedback process, ONC charged the HITAC to establish a new USCDI Task Force for 2021 to make specific recommendations on the content in the Draft USCDI v2, and to provide feedback on the entire process of expanding the USCDI in future versions.

ONC CHARGES TO THE USCDI TASK FORCE

Overarching Charge

The USCDI Task Force 2021 was charged with reviewing and providing feedback on the Draft USCDI Version 2 content and process.

Detailed Charge

The Task Force's specific charges were to:

1. **(Delivered April 15, 2021)** Evaluate Draft USCDI v2 and provide HITAC with recommendations for:

    1a - Data classes and elements from USCDI v1 including applicable standards version updates

    1b - New data classes and elements from Draft USCDI v2 including applicable standards

    1c - Level 2 data classes and elements not included in Draft USCDI v2

2. **(Delivered June 9, 2021)** Evaluate the USCDI expansion process and provide HITAC with recommendations for:

    2a - ONDEC submission system improvements

    2b - Evaluation criteria and process used to assign levels to submitted data classes and elements

    2c - Prioritization process used by ONC to select new data classes and elements for Draft USCDI v2

3. **(Due September 9, 2021)** Provide recommendations on ONC priorities for the USCDI version 3 submission cycle

2

ADDITIONAL BACKGROUND INFORMATION

The Task Force (TF) includes an engaged group of subject matter experts from across various stakeholder groups, including direct patient care, patient advocacy, health IT development, standards development organizations, and others. The roster included in Appendix A to this document reflects the TF membership at the time these recommendations were finalized.

On June 9, 2021, the USCDI TF delivered its recommendations to the full HITAC regarding the USCDI expansion process. All 22 recommendations were unanimously approved by the HITAC. These recommendations were then transmitted to the National Coordinator for consideration. Key recommendations in that report included:

1. Implement changes to the ONDEC submission system to improve usability and accessibility to a broader set of potential contributors with an emphasis on education and inclusion of stakeholders who have not traditionally participated in the standards development process, such as patients, their advocates, and public health professionals.
2. Promote awareness and development of high priority data elements within each level so that they can be matured quickly for inclusion in a future version of USCDI.
3. Make modifications to the Leveling Criteria to support the advancement of data classes/elements that may apply to a narrow stakeholder group when the impact is high.
4. Make additions to the Prioritization Criteria to promote advancement of data elements that address goals of health equity and health data equity, as well as public health and other identified high priority initiatives and use cases, which may change over time.

Recommendations

INTRODUCTION

The focus of the 2021 USCDI TF in its Phase 3 work was to make specific recommendations on ONC priorities for the USCDI version 3 submission cycle, focusing on how best to implement ONC's new priorities for selecting data elements for inclusion in the draft of USCDI version 3. These new prioritization criteria include mitigating health and healthcare disparities, addressing the needs of underserved stakeholders, and addressing public health reporting, investigation, and emergency responses.

TASK FORCE RECOMMENDATIONS

High Priority Use Cases and Stakeholder Groups

- **USCDI-TF-2021-Phase 3_Recommendation 01 – ONC should prioritize and encourage the advancement of data elements/classes that support high priority use cases.**
    - The TF applauds the specification of the above priority Areas of Focus for USCDI V3 and suggests the following for future prioritization:
        - Patient access
        - Value-based care delivery
        - Cost and efficiency improvements including avoiding duplicative services
        - Shared care planning/transitions of care
        - Telehealth and remote care
        - Patient generated health data (PGHD), including patient reported outcomes (PROs) and device data
        - Patient safety
        - Disaster preparedness and pandemic response
        - Population health
        - Precision medicine
        - Research
        - Digital quality measures
        - Registries

- **USCDI-TF-2021-Phase 3_Recommendation 02 – ONC should assign staff champions to focus on and support the USCDI-related needs of the following stakeholders and use cases:**
    - Patients/caregivers
    - Public health, registries, and pandemic-related interoperability
    - Minority use cases

High Priority Data Classes and Elements

- **USCDI-TF-2021-Phase 3_Recommendation 03 – ONC should prioritize and encourage the advancement of the following high priority data elements:**
  - Advance Directives including Durable Power of Attorney for Healthcare (DPAHC) and Physician's/Medical Orders for Life Sustaining Treatment (POLST/MOLST)
  - Functional Status/Disability
  - Disability Status
  - Functional Status/limitations
  - Cognitive Status
  - Pregnancy Status
  - Health Insurance Information
  - DICOM Image Files

- **USCDI-TF-2021-Phase 3_Recommendation 04 – ONC should include all clinical note types defined in the LOINC Document Ontology in USCDI V3**
  - The TF recognizes that this ontology includes a large number of note types beyond the 13 types in the C-CDA implementation guide and the 4 explicitly called out in ONC's certification program.
  - The TF particularly recommends the inclusion of Operative Notes, which are of high value for patients.
  - The TF recommends that ONC work with HL7 to establish guidance on the appropriate grouping and inclusion of the additional clinical note types in C-CDA in the absence of fully defined templates for each type.

- **USCDI-TF-2021-Phase 3_Recommendation 05 – ONC should specifically consider and prioritize the data required to support a robust API/app ecosystem.**

5

○ The USCDI's relatively limited data set and other technical limitations of EHR APIs may hinder developers from building apps that meet real-world use cases. Recent research of health systems' use of patient-facing APIs shows that half of health systems report that EHR-tethered portals offer better functionality than the third-party app ecosystem. Expansion of USCDI is a key factor influencing the rate of progress in API app development and use at scale. For example, until family health history, cognitive status, functional status, or pregnancy status are included as standardized data elements in the USCDI, app developers cannot effectively integrate those data into apps and uses at scale, for providers and patients alike. Conversely, so much more can be done to improve health equity and address social determinants of health with new apps now that SDOH data elements have been added to USCDI for the first time.

● **USCDI-TF-2021-Phase 3_Recommendation 06 – ONC should prioritize the inclusion in USCDI of data elements requested by Public Health stakeholders despite current infrastructure and interoperability challenges.**
  ○ Advancement and adoption of priority data elements for public health should proceed in parallel with efforts to improve public health data systems so that the standardized interoperability and exchange necessary to respond to public health threats become available as soon as possible.

USCDI Advancement Process

● **USCDI-TF-2021-Phase 3_Recommendation 07 – ONC should define and adopt a clear and extensible structure for USCDI data classes and elements to improve the clarity of definitions and enable the industry to interpret them consistently.**
  ○ Add precision to data class and element definitions and specifications to enable users to understand, implement, extend, and refine them with future submissions for new USCDI content.
  ○ Align the definitions of USCDI data classes and elements with the data structures of prevailing exchange specifications and common data models.
    ■ Specifically, ONC's use of "Data Element" in the USCDI should align with the notion of **Element** as used in a FHIR resource, and a **field** in a Common Data Model table. In this way, Data Elements are not typically used on their own, but rather assembled into a "Data Class" whose structure defines the data "shape" in a manner similar to a FHIR **Resource** or data **table** in a Common Data Model.
  ○ Provide a mechanism for defining data classes and elements with various levels of specificity.

6

- ■ Within the data structure defined by a Data Class, the USCDI should explicitly represent subtypes as sharing the same structure, but with further specificity or constraint. For example, SDOH problems should be identified as a subtype of the core "Problem" structure so that they are accompanied by the same core Problem attributes (e.g. date of diagnosis, date of resolution) rather than being an entirely separate kind of entity.
  - ○ See details in the proposal submitted by RTI International

- ● **USCDI-TF-2021-Phase 3_Recommendation 08 – For data classes/elements included in a published USCDI version, ONC should, where possible, specify exemplar technical specifications, implementation guides, data models, and/or "starter value sets" that ONC deems to meet the USCDI requirement.**
  - ○ This information should be distinct from the details provided by the submitter of the data class/element

  - ○ Starter value sets should share a common extensible structure and specify items that would be included within the data class if such data are collected and exchanged. These value sets would be expected to evolve over time in response to stakeholder input and evolving standards.
  - ○ Starter value sets could reside in the Interoperability Standards Advisory (ISA), the Value Set Authority Center (VSAC), or elsewhere with links between the applicable sites.
  - ○ Recommend starter value sets for the Clinical Tests and SDOH Assessments data elements are provided in **Appendix B** with associated standard LOINC codes.

- ● **USCDI-TF-2021-Phase 3_Recommendation 09 – ONC should change the requirement for advancement of a proposed data class/element to Level 2 from exchange between 4 HIT vendors to exchange between 2 HIT vendors.**

Additional TF Considerations

During its Phase 3 meetings TF members discussed a number of topics related to but not directly bearing on ONC's specific charges to the TF. The following areas of consideration reflect broad stakeholder representation within the TF and public commenters, and the enthusiasm that TF members have to support nationwide interoperability. They are shared with the HITAC with the hope that they inform current and future deliberations, priority setting, and recommendations to the National Coordinator.

- ● **ONC's guidance (e.g., priorities, clarifications, FAQs) to support providers, HIT vendors, HIE/HINs, patients/caregivers, and other stakeholders in compliance with the 2022-23 requirements to exchange all Electronic Health Information (EHI) at both the individual and population levels.**

- ○ ONC should encourage stakeholders to identify and prioritize data classes and elements that may be difficult to access, exchange and/or use, in the absence of inclusion in USCDI, when required by expanded scope of the Information Blocking and HIT Certification rules.

- **ONC's development and implementation of "write access" API requirements relevant to USCDI data classes and elements.**
  - ○ Patients, caregivers, social-service and community-based providers may be the primary source of SDOH and other data, including outcomes which are especially valuable for value-based care. The ability to exchange data between these sources and provider EHRs would be highly valuable for facilitating and managing care.
  - ○ Read and write APIs would be particularly beneficial to support public health interoperability use cases.

- **ONC's encouragement of the use of FHIR Questionnaires to address USCDI data collection gaps, especially PGHD, SDOH and data utilized in research.**

- **ONC's process to review, document and validate non-certified HIT systems that share USCDI data.**

- **ONC's promotion and support of the development of technical implementation guides to reinforce public health use cases.**

Additional HITAC Recommendation

Note: The following recommendation was not discussed or recommended by the USCDI TF but was discussed during the HITAC meeting on September 9, 2021 with the committee voting to add to this recommendation.

- **USCDI-TF-2021-Phase 3_Recommendation 10 – ONC should charge the HITAC to convene the USCDI Task Force to discuss the HITAC recommendation that ONC support a social model of disability including the advancement of relevant data elements.**

Appendix A

TASK FORCE ROSTER

Name	Organization
Leslie Kelly Hall (Co-Chair)	Engaging Patient Strategy
Steven Lane (Co-Chair)	Sutter Health
Ricky Bloomfield	Apple
Hans Buitendijk	Cerner
Grace Cordovano	Enlightening Results
Jim Jirjis	HCA Healthcare
Ken Kawamoto	University of Utah Health
John Kilbourne	VA
Leslie Lenert	Medical University of South Carolina
Clement McDonald	National Library of Medicine
Aaron Miri	The University of Texas at Austin, Dell Medical School and UT Health Austin
Brett Oliver	Baptist Health
Mark Savage	Savage Consulting
Michelle Schreiber	CMS
Abby Sears	OCHIN
Sasha TerMaat	Epic
Andrew Truscott	Accenture
Sheryl Turney	Anthem, Inc.
Daniel Vreeman	RTI International
Denise Webb	Indiana Hemophilia and Thrombosis Center

Appendix B

EXAMPLE CLINICAL TESTS AND ASSOCIATED VOCABULARY STANDARDS:

Specialty	LOINC Test Name	LOINC code
Cardiology	12 lead EKG panel	34534-8
Cardiology	Ambulatory blood pressure monitor study	92846-5
Cardiology	Ambulatory cardiac rhythm monitor (Holter) study	18754-2
Cardiology	Cardiac 2D echo panel	34552-0
Cardiology	Cardiac electrophysiology study	18750-0
Cardiology	Cardiac left ventricular segmental wall motion by angiography panel	78950-3
Cardiology	Cardiac left ventricular segmental wall motion by echo panel	Pending
Cardiology	Cardiac nuclear imaging SPECT panel	82654-5
Cardiology	Cardiac stress echo study	59282-4
Cardiology	Cardiac stress EKG study	Submitted to RI
Cardiology	Tilt table study	46213-5
Cardiology	Coronary angiography panel	78895-0
Cardiology	Six-minute walk test	64098-7
Endocrinology	Bone density quantitative measurement by DXA panel	83311-1
Endocrinology	Bone density quantitative ultrasound study	Pending
Gastroenterology	Anorectal manometry study	Submitted to RI
Gastroenterology	Capsule endoscopy study	Pending
Gastroenterology	Colonoscopy+Ultrasound study	97100-2

Gastroenterology	Endoscopic ultrasound study	Pending
Gastroenterology	ERCP study	28016-4
Gastroenterology	Esophageal manometry study	51393-7
Gastroenterology	Esophageal pH monitoring study	Submitted to RI
Gastroenterology	Flexible sigmoidoscopy +Ultrasound study	97101-0
Gastroenterology	Colonoscopy study	18746-8
Gastroenterology	Flexible sigmoidoscopy study	18753-4
Gastroenterology	Endoscopy study	18751-8
Neurology	EEG study	11523-8
Neurology	Nerve conduction study panel	98604-2
Neurology	Electromyogram study	18749-2
Neurology	Nystagmogram study	29754-9
Neurology	Video EEG study	92050-4
Obstetrics	Routine prenatal assessment panel	Pending
Ophthalmology	Color vision panel	98495-5
Ophthalmology	Electroretinography (ERG) panel	79894-2
Ophthalmology	Keratometry panel	95298-6
Ophthalmology	Lensmeter panel	95318-2
Ophthalmology	Multifocal electroretinography (mfERG) panel	96227-4
Ophthalmology	Objective refraction panel	79898-3
Ophthalmology	Optical coherence tomography panel	57119-0
Ophthalmology	Pattern electroretinography (PERG) panel	96246-4
Ophthalmology	Subjective refraction panel	79895-9
Ophthalmology	Tonometry panel	79896-7
Ophthalmology	Visual acuity panel	98497-1

Otolaryngology/Audiology	Evoked potential study	77199-8
Otolaryngology/Audiology	Pure tone threshold audiometry panel	89015-2
Pulmonary	Endobronchial ultrasound	Pending
Pulmonary	Bronchoscopy study	18744-3
Pulmonary	Spirometry panel	81459-0
Pulmonary	Polysomnography panel	90568-7
Pulmonary	Pulmonary function panel	81458-2
Urology	Uroflowmetry panel	80525-9
Urology	Post void bladder volume by US	Submitted to RI

EXAMPLE SDOH ASSESSMENTS AND ASSOCIATED STANDARDS:

- The Protocol for Responding to and Assessing Patients' Assets, Risks, and Experiences (PRAPARE) - LOINC 93025-5
- Accountable Health Communities (AHC) Health-Related Social Needs (HRSN) Screening Tool - LOINC 96777-8
- Perceived Stress Protocol - LOINC 64394-0
- US Food Security Surveys - LOINC 96576-4, 95361-2, 95246-5
- WE CARE Survey - LOINC 96447-8
- Patient-Reported Outcomes Measurement Information System (PROMIS) measures - LOINC 75418-4, 75421-8, 75420-0, 75419-2
- Humiliation, Afraid, Rape, Kick (HARK) questions for intimate partner violence - LOINC 76499-3
- Hunger Vital Sign (HVS) - LOINC 88121-9